AMERICAN FRESH JUICE COUNCIL

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November 30, 1999

Docket #97N-0511
Dockets Management Branch
HFA-305
Food & Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE Comments to the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) December 8-9 1999 meeting to discuss recent research and other information related to performance criteria for fresh juice.

Dear Sir or Madam:

The American Fresh Juice Council (AFJC) appreciates the opportunity to offer comments in relation to recent research and studies regarding fresh citrus juice production. Research attributed to the subject of internalization of microorganisms within fresh citrus fruit, stands to determine the future viability of the fresh juice market. In the short-term, the decisions from this meeting will influence the rule making process for fresh juice. However, the long-term impact of the data presented at this meeting, may reach beyond juice to fresh fruits and vegetables. This meeting is the time to decide if the internalization theory has "practical" merit. The accusation that surface cleansing and sanitation may not be sufficient to prepare fresh citrus fruit for extraction, can easily and logically be extended to fresh table fruit. The AFJC is hopeful that the NACMCF will lay this issue to rest on December 08, 1999, preventing any unfortunate ripple effects.

Preface

Before commenting specifically on the issue of internalization, the AFJC would like to address the current industry setting. All evidence known to the AFJC indicates that outbreaks associated with unpasteurized citrus juices in the United States, have been

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"situation specific." There is no evidence that the fruit from which the juice was made was an inherent threat. The AFJC knows of no illnesses associated with the consumption of fresh citrus fruit containing a clinical pathogen. There is seemingly a n-k-focus of agency efforts in this case. The internalization studies focus on the product category and raw agricultural product, rather than on the producer and production practices. If contaminations are caused by specific practices, the agency should pursue those sources. If the practice linked to a contamination would have just as easily infected any other food product in the same circumstance, attributing the contamination to citrus fruit is not appropriate. Playing "what-if games can be intriguing. However, throughout this process, let us not lose sight of basic food safety principles. Would all known contaminations of fresh citrus juice have been prevented by strict adherence to GMP's, quality HACCP plans, surface 5-log reductions and rigid inspection programs? Experts contacted, believe that these steps would have made the difference.

Perspective:

It is important that the NACMCF understand the perspective of the fresh juice industry when deliberating on the issue of internalization. The FDA, and much of the processed food industry appear to operate under the false impression that pasteurization is simply an adjustment to the production process, providing added safety, with minimal impact on the health and taste benefits of the juice product. The fresh juice industry (producers and consumers) holds an entirely different view of pasteurization. The fresh industry knows its customers and clearly understands why consumers make the purposeful choice to purchase unpasteurized juice. These customers want an unprocessed product. These consumers are not enamored with the concept of a "minimally processed" product. The superior taste profile drives some consumers to fresh juice. Others prefer the natural unprocessed juice for its healthful properties. Regardless of which attribute drives their purchase decision more strongly, one thing is certain. Flash pasteurization, in the eyes of fresh juice buyers, does not alter the product. **In the eyes of these consumers, flash pasteurized juice is an entirely different product.** ~~To~~ a mandated 5-log reduction, after the extraction step, would ~~eliminate~~ ***an industry and a healthful product under high demand by American consumers.*** The NACMCF should recommend that the FDA focus its efforts on: (1) specific industry practices that could be modified or eliminated to enhance the safety of the industry; (2) recommend a comprehensive program of production standards and inspection that would provide an added assurance of compliance; (3) pursue producers operating outside known safety parameters.

In regards to "alternate technologies", there simply are not any viable alternatives to pasteurization. Alternate technologies are either unaffordable or ineffective on opaque juice products. Countless discussions have centered on this subject, only to identify pasteurization as the only viable alternative for citrus juice. Considering the consumer response to additional processing, mandating a "post extraction kill-step" would drive many firms out of business.

Internalization:

If the question of internalization deserves any consideration at all, it deserves sound science based on true industry practices and reasonable assumptions. It is critical that the assumptions, on which the research is based, are matched closely to what really occurs in nature and common industry practices. If this is not the case, then the agency places the industry in an inherently unfair and unenviable position. The agency merely has to prove a positive; that under some circumstance, no matter how improbable, internalization can occur in the raw commodity. The industry, with its limited resources, must then prove the negative; that internalization cannot occur under any circumstance. Common sense and reason must play into this equation. It is the AFJC's hope that the NACMCF will listen to the reasoned assumptions made by the industry, as it addresses the internalization question

Beyond assumptions, the research considered by the NACMCF must be practical and logical. Has there ever been a single reported illness attributed to an apparently wholesome piece of fresh citrus fruit? Is it any more likely that internalization would occur in an orange than an ill person infecting others by mixing reconstituted juice at the local diner? Of course it isn't. Is it practical to assume that ifinternalization does occur in apparently wholesome fresh citrus fruit, that of the billions of oranges expressed into juice in Florida since 1996, someone would have reported ill, or a lab result (taken on every batch) would have provided a link? The fact remains, that of the thousands of lab tests performed in Florida during this time frame, there was not a single pathogen detection.

It is interesting to note that when the AFJC began contacting members of the scientific community to seek expert testimony on the subject of internalization, it could not find one reputable and experienced scientist to speak to the assertion. The reason for the reluctance of these individuals to speak to this subject was consistent. The scientific community had never directed specific research to the internalization of clinical pathogens within fresh citrus fruit, as it was never considered an issue. In other words, nothing had ever occurred that would indicate that internalization was a reasonable possibility or an issue worthy of study. All research presented at the December 08, 1999 meeting was initiated in response to FDA's allegation of internalization.

The AFJC firmly believes that the Florida safety and sanitation program (for unpasteurized juiced producers) is producing enviable results. Some firms in other states have developed remarkable safety systems, but it is clear that Florida has all of the elements of a "model plan". Florida has established rules to regulate the production of fresh citrus juice in small roadside operations and larger continuous production juice plants (each category is subject to specific safety/sanitation and inspection provisions). Since the implementation of these rules approx. three years ago, the AFJC is not aware of a food safety incidence traced to a Florida facility. Either fresh citrus fruit does not, on occasion internalize clinical pathogens; the Florida model (Strict GMP's, HACCP, 5-log AND Inspection) is well worth emulating, or both. Something is going right in Florida

that is worthy of further study. The Florida fresh citrus juice Pilot Plant should contribute the answer to this question. Pilot Plant records should be studied thoroughly by CFSAN and the NACMCF, so that the scientific community is provided full benefit of the most extensive and expensive fresh juice "observation" project to date.

General Remarks:

The focus on internalization is obviously a means to lead the industry to a juice processing or treatment step. Questioning the very assumption, on which the original 5-log surface treatment was proposed, is the straightest shot to pasteurization. However, the AFJC cautions that pasteurization and "alternate technologies" are not a cure-all. The AFJC would much prefer that the industry invest in sanitation measures on the front end of processing, to practice prevention, rather than rely on a rear-loaded kill step. The FDA's July apple workshop in Washington indicated that much work remains to be done on small volume pasteurization technology and standards. Some products are being marketed to small-scale producers that are of questionable value. Pushing small volume producers toward low volume flash pasteurization units may be ill advised. If small producers are to place their faith in something, they should place it in the safety and sanitation practices that produce a clean raw product from a clean facility, run by clean people. The internalization data provided by Dr. Ismail, Dr. Pao, and Dr. Strobos bear out this assertion Citrus fruit, under real word conditions, does not internalize harmful microorganisms. Therefore, the best course of action for producers of all citrus juices remains:

- Strict Adherence to **GMP's.**
- A quality 5-log HACCP plan.
    - The AFJC stands firm behind its longstanding recommendation that HACCP requirements are a valid requirement for all producers of citrus juices. Although the topics on this NACMCF agenda are specifically related to fresh unpasteurized juices, the AFJC maintains that the FDA HACCP requirement should be imposed on producers of processed and fresh juices. Likewise, the AFJC recommends that a HACCP requirement be extended to juice producers of all size and variation. There is no logical reason why the size of a facility should have a bearing on the applicability of safety standards.
    - Compliance doesn't come cheap. An AFJC survey indicated that AFJC members alone, have already expended several million dollars complying with FDA juice regulations since 1996. This is a significant commitment that should be required of all juice producers.
- **Inspection.** Reputable producers will always seek ways to improve and produce the safest and highest quality product possible. However, there will always be operators who do what is "inspected" rather than what is "expected". For the latter group, FDA should support a nationwide inspection effort. This program could be a cooperative effort between USDA, FDA and State Dept's of Agriculture. This works in Florida and could work elsewhere.

CFSAN seemingly supports this model in a paper titled "Potential for Internalization, survival and Growth of Human Pathogens within Fruits and Vegetables". This paper highlights the importance of appropriate sanitation practices within fresh juice facilities. Surely, this supports the AFJC's continued call for a national inspection program for fresh juice production.

Thank you for your consideration of these comments.

Sincerely

J. Peter Chaires
President – AFJC
Associate Vice President – Florida Gift Fruit Shippers Association

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